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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,707	01/19/2007	Osamu Ohara	3190-100	9479
33432 7590 04/27/2009 KILYK & BOWERSOX, P.L.L.C. 400 HOLIDAY COURT SUITE 102 WARRENTON, VA 20186				
EXAMINER				
DESAI, ANAND U				
ART UNIT		PAPER NUMBER		
1656				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/594,707

Applicant(s)

OHARA ET AL.

Examiner

ANAND U. DESAI

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-23 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 10-22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 7-9 is/are allowed.
- 6) ☒ Claim(s) 5 and 6 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This office action is in response to the amendment filed on December 30, 2008. Claim 4 has been cancelled. Claims 2, 3, and 10-22 have been withdrawn previously.
2. Claims 1, 5-9, and 23 are currently pending and are under examination.

Withdrawal of Rejections

3. The rejection of claims 1, 4-9, and 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the amendments to the claims.
4. The rejection of claims 1, 4-9, and 23 under 35 U.S.C. 102(b) as being anticipated by Venter et al. (WO 2002/068579 A2) is withdrawn based on the amendments to the claims.

Pending Rejections

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Regarding claim 5, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). What other types of mutations are within the metes and bounds of the claim?

8. It is unclear how the isolated polynucleotide that hybridizes to the isolated nucleic acid that encodes SEQ ID NO: 2 or the isolated nucleic acid molecule that is identified as SEQ ID NO: 1 (items (b) and (a) in claim 1) would encode a protein that accelerates activation of Cdc42. It appears the polynucleotide of claim 6 would be the complement nucleic acid sequence.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is rejected under 35 U.S.C. 112, first paragraph, Written Description, because the disclosure does not direct one of ordinary skill in the art to the genus of mutated polynucleotides of one to ten nucleotides that will encode a protein that accelerates the activation of Cdc42.

The Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, Paragraph 1, "Written Description" Requirement, published at Federal Register, Vol. 66, No. 4, pp. 1099-1111 outline the method of analysis of claims to determine whether adequate written description is present. The first step is to determine what the claim as a whole covers, i.e., discussion of the full scope of the claim. Second, the application should be fully reviewed to

understand how applicant provides support for the claimed invention including each element and/or step, i.e., compare the scope of the claim with the scope of the description. Third, determine whether the applicant was in possession of the claimed invention as a whole at the time of filing. This should include the following considerations: (1) actual reduction to practice, (2) disclosure of drawings or structural chemical formulas, (3) sufficient relevant identifying characteristics such as complete structure, partial structure, physical and/or chemical properties and functional characteristics when coupled with a known or disclosed correlation between function and structure, (4) method of making the claimed invention, (5) level of skill and knowledge in the art and (6) predictability of the art. For each claim drawn to a single embodiment or species, each of these factors is to be considered with regard to that embodiment or species. For each claim drawn to a genus, each of these factors is to be considered to determine whether there is disclosure of a representative number of species that would lead one skilled in the art to conclude that applicant was in possession of the claimed invention. Where skill and knowledge in the art is high adequate written description would require fewer species to be disclosed than in an art where little is known; further, more species would need to be disclosed to provide adequate written description for a highly variable genus.

First, what do the claims as a whole cover? Claim 5 is drawn to an isolated polynucleotide with a mutation of one to ten nucleotides in the nucleotide sequence of the polynucleotide in independent claim 1, wherein the polynucleotide encodes a protein that accelerates the activation of Cdc42.

Second, how does the scope of the claims compare to the scope of the disclosure? The disclosure contains the same language found in claim that is the disclosure states the polynucleotide can have from one to ten nucleotides mutated in the polynucleotide sequence.

Third, the factors need to be considered.

- (1) What was actually reduced to practice?

The isolation of SEQ ID NO: 1 that encodes a guanine nucleotide exchange factor protein identified as SEQ ID NO: 2 is reduced to practice and shown to accelerate the activation of Cdc42.

- (2) Is there disclosure of drawings or structural chemical formulas? / (3) Are there sufficient relevant identifying characteristics disclosed?

The disclosure does not identify any specific nucleic acids with any structural modifications that result in the description of a genus of polynucleotides that encode proteins that accelerates the activation of Cdc42.

- (4) Is there at least one method of making the claimed invention disclosed?

The method of making SEQ ID NO: 2 is disclosed.

- (5) What is the level of skill in the art and what knowledge is present in the art? / (6) What is the level of predictability of the art?

The level of predictability in this art is low, and until the modifications structural to functional analysis is conducted, there is no information upon which to base a prediction of what molecule might be suitable to activate Cdc42.

Thus, having analyzed the claims with regard to the Written Description guidelines, it is clear that the specification does not disclose a representative number of species which would lead one skilled in the art to conclude that applicant was in possession of the claimed invention.

Claim Objections

11. Claim 23 is objected to because of the following informalities:
12. The standard Markush format is selected from the group consisting of A, B, and C. Suggest commas instead of semi-colons to separate the members.
13. Appropriate correction is required.

Conclusion

14. Claims 1 and 7-9 are allowable.
15. Claims 5 and 6 are rejected.
16. Claim 23 is objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ANAND U DESAI/
Primary Examiner, Art Unit 1656
April 23, 2009